

Jezil

contains the active ingredient gemfibrozil

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Jezil.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking Jezil against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What Jezil is used for

Jezil is used to help control high levels of cholesterol and triglycerides, which are fat-like substances in the blood.

Jezil belongs to a group of medicines called fibric acid derivatives or fibrates. The exact way in which Jezil works is not known but it is thought to work by reducing the "bad" (LDL) cholesterol and triglycerides while raising the "good" (HDL) cholesterol. This helps keep your blood vessels unblocked and decreases the risk of heart disease to prevent heart attacks, angina and stroke.

Ask your doctor if you have any questions about why Jezil has been prescribed for you.

Your doctor may have prescribed Jezil for another reason.

Jezil is not recommended for use in children, as its safety and effectiveness in children have not been established.

Jezil is available only with a doctor's prescription.

There is no evidence that Jezil is addictive.

Before you take Jezil

When you must not take it

Do not take Jezil if you are allergic to medicines containing gemfibrozil (e.g. Lopid, Gemhexal or Lipazil), or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips, mouth, throat or neck; difficulty in swallowing or breathing, wheezing or shortness of breath.

Do not take Jezil if you have:

- * severe liver disease
- * severe kidney disease
- * gallstones or gall bladder disease
- * type I hyperlipoproteinaemia (a specific type of blood fats disorder).

Do not take Jezil if you are pregnant or breastfeeding.

Your baby may absorb this medicine in the womb or from breast milk and

therefore there is a possibility of harm to the baby.

Do not take Jezil if you are currently taking repaglinide (Novonorm), a medicine used in the management of diabetes.

Taking these two medicines together may cause an excessive drop in your blood sugar levels.

Do not take Jezil if the expiry date (Exp.) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take Jezil if the packaging shows signs of tampering or the tablets do not look quite right.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- * kidney problems
- * jaundice (yellowing of the skin or eyes) or other liver problems
- * gallstones or gall bladder problems
- * diabetes
- * a thyroid condition.

Tell your doctor if you have had muscle pain, tenderness or weakness while you were taking other medicines for high cholesterol or triglycerides (e.g. simvastatin, pravastatin, atorvastatin and fluvastatin).

If you have not told your doctor about any of the above, tell them before you start taking Jezil.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may be affected by Jezil, or may affect how well it works. These include:

- * medicines to prevent blood clots, such as warfarin (Coumadin, Marevan)
- * other medicines used to treat high cholesterol or triglycerides, such as simvastatin (Lipex, Zocor), pravastatin (Pravachol), atorvastatin (Lipitor), fluvastatin (Lescol, Vastin), colestipol (Colestid Granules)
- * repaglinide (Novonorm), a medicine used to treat diabetes.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Jezil.

How to take Jezil

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the bottle, ask your doctor or pharmacist.

How much to take

The usual dose is one tablet (600 mg) twice a day.

How to take Jezil

Swallow the tablets with a glass of water.

When to take Jezil

Take one tablet in the morning and in the evening, at about the same time each day.

This will help you remember when to take it and will have the best effect.

Take Jezil on an empty stomach, half an hour before food.

Food can interfere with the absorption of Jezil.

If taking the tablets on an empty stomach makes you feel unwell, you may take them with food.

How long to take Jezil

Keep taking Jezil for as long as your doctor recommends.

Jezil helps to control high cholesterol and triglyceride levels but does not cure it. To properly control your condition Jezil must be taken every day on a long-term basis, even if you feel well.

If you forget to take Jezil

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

Do not take a double dose to make up for the dose you missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much Jezil (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Jezil. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much Jezil, you may feel sick (nausea) and vomit, have stomach pain, diarrhoea, muscle and joint pain.

While you are taking Jezil

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking Jezil.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking Jezil.

If you become pregnant while taking Jezil, tell your doctor immediately.

Visit your doctor regularly so that they can check on your progress.

Your doctor may do some tests to check your cholesterol and triglyceride levels, your blood and liver function.

Since Jezil is to be taken regularly every day, keep a continuous supply of medicine so you don't run out, especially over weekends or on holidays.

Things you must not do

Do not use Jezil to treat any other conditions unless your doctor tells you to.

Do not give Jezil to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful driving or operating machinery until you know how Jezil affects you.

Jezil generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Jezil may cause dizziness in some people.

Lifestyle changes that may help reduce the chance of coronary heart disease

The chances of having coronary heart disease (CHD) may be increased by several other factors, including high blood pressure, cigarette smoking, diabetes, excess weight, family history of CHD, being a male and being a woman who has reached menopause. Lowering high cholesterol can help reduce your chances of having CHD.

Some self help measures suggested below may help your condition and help reduce your chances of having CHD:

- * Diet - continue the low fat diet recommended by your doctor, dietician or pharmacist. The cholesterol in the foods you eat contributes to high blood cholesterol and triglyceride levels.
- * Weight - your doctor may advise you to lose weight if you are overweight.
- * Exercise - make exercise a part of your routine - walking is good. Check with your doctor first before starting exercise.
- * Smoking - your doctor will advise you to stop smoking
- * Alcohol - limit your alcohol intake.

Talk to your doctor, pharmacist, or dietician about these measures and for more information.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Jezil.

Jezil helps most people with high cholesterol and triglyceride levels, but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- * heartburn, stomach pain, feeling sick (nausea), vomiting, change in taste
- * diarrhoea, constipation
- * tiredness
- * dizziness
- * headache
- * blurred vision
- * skin rash
- * decreased sex drive.

The above list includes the more common and milder side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- * depression
- * tingling in the hands or feet
- * severe stomach pain and discomfort, burping and wind, indigestion or feeling sick, especially after eating fatty foods
- * yellowing of the skin or eyes (jaundice)
- * painful, weak or tender muscles
- * joint pain
- * tiredness, shortness of breath and

looking pale

- * signs of frequent infections such as fever, chills, sore throat or mouth ulcers.

The above list includes the more serious side effects of Jezil which may require medical attention. Serious side effects are rare.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- * signs of an allergic reaction include swelling of the face, lips, mouth, throat or neck which may cause difficulty swallowing or breathing.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients.

Some of these side effects (e.g. changes in liver function) can only be found when your doctor does tests from time to time to check your progress.

After using Jezil

Storage

Keep Jezil where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep your tablets in a cool dry place where the temperature stays below 30 degrees C.

Do not store Jezil or any other medicine in the bathroom or near a sink.

Do not leave Jezil in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Jezil, or your tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

Jezil is an oval, white tablet marked PD 737.

Each bottle of Jezil contains 60 tablets.

Ingredients

The active ingredient in Jezil is gemfibrozil. Each tablet contains 600 mg of gemfibrozil.

The tablets also contain the following inactive ingredients:

- * colloidal anhydrous silica
- * calcium stearate
- * microcrystalline cellulose
- * pregelatinised maize starch
- * hydroxypropylcellulose
- * macrogol 3350
- * polysorbate 80
- * methyl hydroxybenzoate
- * propyl hydroxybenzoate
- * hypromellose
- * candellila wax
- * Opaspray White K-1R-7000
(includes colour titanium dioxide [E 171]).

Jezil tablets are gluten free.

Supplier

Jezil is supplied by:

Alphapharm Pty Limited

(ABN 93 002 359 739)

Chase Building 2

Wentworth Park Road

Glebe NSW 2037

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Medical Information

Phone: 1800 028 365

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